petitioner is required to include in the petition.

FDA estimates the burden resulting from the requirements of § 101.12(h) as follows:

TABLE 4.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Operating & Maintenance Costs
101.12(h)	5	1	5	80	400	$400,000

There are no capital costs associated with this collection.

Since the enactment of the 1990 amendments that revised the act by adding section 403(q), FDA has received nine petitions to amend existing reference amounts. Based upon these submissions, FDA estimates that no more than five such petitions will be submitted annually. The estimate for operating and maintenance costs is based on the average cost of conducting a consumer survey to support a reference amount petition.

Dated: May 22, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–13536 Filed 5–29–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96F–0164]

Asahi Denka Kogyo K.K.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Asahi Denka Kogyo K.K. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of sodium 2,2'-methylenebis(4,6-di-*tert*-butylphenyl)phosphate as a clarifying agent in high density polyethylene intended for use in contact with food.

DATES: Written comments on the petitioner's environmental assessment by July 1, 1996.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 6B4504) has been filed by Asahi Denka Kogyo K.K., 2–13 Shirahata 5–Chome, Urawa City, Saitama 336, Japan. The petition proposes to amend the food additive regulations in § 178.3295 *Clarifying agents for polymers* (21 CFR 178.3295) to provide for the safe use of sodium 2,2'-methylenebis(4,6-di-*tert*-butylphenyl)phosphate as a clarifying agent in high density polyethylene intended for use in contact with food.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before July 1, 1996, submit to the Dockets Management Branch (address above) written comments. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the Federal Register. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the Federal Register in accordance with 21 CFR 25.40(c).

Dated: May 14, 1996.

George H. Pauli,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 96–13464 Filed 5–29–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95E–0385]

Determination of Regulatory Review Period for Purposes of Patent Extension; PRECOSE™

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for PRECOSE™ and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis